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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,863	09/17/2003	Steven Walak	10123/00401	8458
7590 04/19/2007 Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038			EXAMINER WYSZOMIERSKI, GEORGE P	
			ART UNIT 1742	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
3 MONTHS			04/19/2007	
			DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/666,863	<b>Applicant(s)</b> WALAK ET AL.	
	<b>Examiner</b> George P. Wyszomierski	<b>Art Unit</b> 1742	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/5/07 (Election).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/26/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/17/03, 12/30/04</u> . | 6) <input type="checkbox"/> Other: _____  |

1. Applicant's election without traverse of Group I, claims 1-23 in the reply filed on February 5, 2007 is acknowledged.

*Claim Interpretation*

2. Present claims 8-13, 15, 18-21 and 23 recite or include product-by-process limitations. These limitations will be considered only to the extent that they affect some physical aspect of the products within the scope of the instant claims. It is well-settled that a product-by-process claims defines a product. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process; see *In re Thorpe* (227 USPQ 964, Fed.Cir. 1985). The burden then shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product; see *In re Marosi* (218 USPQ 289, Fed.Cir. 1983).

3. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation in claim 1 of "predetermined operating conditions to which the device will be subjected when deployed within the body" renders these claims indefinite because it is not possible to determine what conditions the devices as claimed will be subject to at some indefinite point in the future.

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. (U.S. Patent 5,514,115) or over WIPO publication 02/36045.

Both Frantzen and WIPO disclose medical devices (e.g. stents and catheters) made of Nitinol alloys and including portions that are in a martensitic state and portions in an austenitic state; see Frantzen column 2, line 31 thru column 4, line 26, or WIPO '045 page 8, lines 9-14 and page 10, lines 8-20. With respect to instant claim 2, any interface between the two such portions in the prior art meet the limitations of this claim. With respect to instant claims 6 and 7, note Frantzen column 3, lines 1-3. With respect to instant claims 8, 15, 18 and 19, the product-by-process limitations in these claims do not patentably define over the prior art for reasons as set forth in item no. 2 supra.

The prior art does not specifically recite the conditions regarding strain that the prior art devices are exposed to or the stability of the martensitic phase in the portions that are martensitic. However, because the prior art devices are both made of the same materials as the claimed devices and are intended for use in substantially the same manner, it is a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention. Thus, a prima facie case of obviousness is established between the disclosures of Frantzen et al. or WIPO '045 and the presently claimed invention.

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6. Claims 2, 9-13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. or WIPO 02/36045, as above, either of which in view of Flomenblit et al. (U.S. patent 5,964,770).

Like Frantzen and WIPO '045, Flomenblit is directed to medical devices such as stents including both martensitic and austenitic portions. With respect to instant claim 2, Flomenblit column 4, lines 23-29 indicate that it was known in the art, at the time of the invention, to construct such devices having the limitations as recited in the instant claim. With respect to instant claims 9-13, 20 and 21, Flomenblit column 6, lines 58-67 indicates it was conventional in the art to employ Nitinol alloys including small amounts of one or more additional materials (besides Ni and Ti) as required by the instant claims. The precise manner by which these additional materials are present is not relevant for reasons as set forth in item no. 2 supra. Thus, the disclosure of Frantzen et al. or WIPO '045, together with the teachings of Flomenblit et al., would have taught devices as presently claimed to one of ordinary skill in the art.

7. Claims 1, 3-8, 14-19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (U.S. Patent 6,923,829).

Boyle discloses implantable medical devices made of nitinol, portions of which are in an austenitic phase and portions in a martensitic phase. With respect to instant claim 2, any interface between the two such portions in the prior art meet the limitations of this claim. With respect to instant claims 8, 15, 18 and 19, the product-by-process limitations in these claims do not patentably define over the prior art for reasons as set forth in item no. 2 supra. With respect to instant claims 14 and 23, Boyle column 9, lines 20-28 indicate that different portions of the material have different chemical compositions, as required by the instant claims.

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The prior art does not specifically recite the conditions regarding strain that the prior art devices are exposed to or the stability of the martensitic phase in the portions that are martensitic. However, because the prior art devices are both made of the same materials as the claimed devices and are intended for use in substantially the same manner, it is a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention. Thus, a prima facie case of obviousness is established between the disclosure of Boyle et al. and the presently claimed invention.

8. Claims 2, 9-13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. in view of Flomenblit et al.

Like Boyle, Flomenblit is directed to medical devices such as stents including both martensitic and austenitic portions. All aspects of Flomenblit as described in item no. 6 supra apply equally as well in this instance. Thus, the combined disclosures of Boyle et al. and Flomenblit et al. would have taught the present invention to one of ordinary skill in the art.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-8, 15-19 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,890,350. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the instant claims and the '350 claims is that the '350 claims make no mention of the austenitic and martensitic phases as required by the instant claims. In making this rejection, the examiner is relying on the case law in *Vogel* supra, in which the Court noted that portions of the specification which provide support for the patent claims may be examined and considered when addressing the issue of whether a claim in an application defines an obvious variation of an invention claimed in a patent. In the present case, the paragraph overlapping columns 7-8 of the '350 patent provides support for an embodiment of that patent in which the superelastic material and plastically deformable material of e.g. '890 claim 1 are austenitic and martensitic, respectively. Thus, the examiner is holding the presently claimed austenitic and martensitic embodiment to be nothing more than an obvious variant of the superelastic and plastically deformable devices as defined in the claims of the '350 patent.

11. Claims 2, 9-13, 20 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S.

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Patent No. 6,890,350 in view of Flomenblit et al. All aspects of the stents of Flomenblit as described in item no. 6 supra apply equally as well to the medical devices as disclosed and claimed in the '350 patent. In view of the claimed combination of superelastic and plastically deformable materials in the '350 claims, the presently claimed austenitic and martensitic materials made of the elements as presently claimed are considered to be obvious variants of those devices of the '350 claims as modified by the teachings of Flomenblit et al.


12. The remainder of the art cited on the attached PTO-892 and 1449 forms is of interest. This art is held to be no more relevant to the claimed invention than the art as applied in the rejections, supra.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. All patent application related correspondence transmitted by facsimile must be directed to the central facsimile number, (571)-273-8300. This Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GPW  
April 16, 2007

  
GEORGE WYSZOMIERSKI  
PRIMARY EXAMINER  
APR 16 2007